Does cryotherapy before drainage increase the risk of intraocular haemorrhage and affect outcome?

A prospective, randomised, controlled study using a needle drainage technique and sustained ocular compression

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Abstract

***Aims/background*—A prospective, randomised, controlled clinical trial was conducted to investigate the effect of performing cryotherapy before drainage of subretinal fluid (SRF) on the incidence of intraocular haemorrhage (IOH) in the management of retinal detachment.**

***Methods*—Eighty eyes of 80 patients with rhegmatogenous retinal detachment requiring SRF drainage were recruited. Thirty four cases were randomised to receive drainage before cryotherapy (drainage, air injection, cryotherapy, and explant = DACE group) while 46 cases had drainage after cryotherapy (cryotherapy, drainage, air injection, and explant = CDAE group). All cases had trans-scleral drainage of SRF using a 27 gauge hypodermic needle combined with prolonged, intraocular hypertension.**

***Results*—There was a low incidence of IOH associated with drainage in both groups with no statistically significant difference between the groups (DACE group = 2.9%; CDAE group = 4.3%; p = 0.43). There was no significant difference between the groups in the rate of anatomical success with a single operation (DACE group = 82.4%; CDAE group = 86.9%; p = 0.38). There was no significant difference between the groups in the visual outcome. An improvement of two Snellen lines or more occurred in 52.9% of the DACE group and in 56.5% of the CDAE group (p = 0.93).**

***Conclusion*—It was concluded that the surgical sequence of applying cryotherapy before drainage of SRF can be safely and effectively performed. The sequences CDAE and CDE, when air injection is not required, along with DACE should all be part of the surgical repertoire for the management of retinal detachments.**

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Although many cases of rhegmatogenous retinal detachment can be successfully managed without drainage of subretinal fluid (SRF),[1] there are specific situations where drainage is advantageous—for example, superior bullous retinal detachments.[2 3] The external drainage of SRF is a potentially dangerous step and can be complicated by intraocular haemorrhage (IOH), retinal perforation, vitreoretinal incarceration, and endophthalmitis.[4] The most common complication is IOH with reported incidences of between 1.7% and 28.3%.[4–10] This complication can have significant morbidity particularly when subretinal blood tracks beneath the macula.[11] The drainage technique used,[5–10] the site of drainage,[3] and the surgical sequence employed have all been implicated as affecting the incidence of IOH. Several authors have suggested a putative benefit of performing drainage before cryotherapy to avoid choroidal vasculature congestion and reduce the risk of IOH.[9 10 12 13] However, the visualisation of retinal breaks using this sequence, particularly through a bubble, can be difficult. In addition, when injection is not required, the hypotony associated with drainage may conversely increase the risk of haemorrhage for subsequent cryotherapy. This is the first prospective, controlled, randomised study to address the question of whether cryotherapy before drainage influences the risk of IOH.

Materials and methods

STUDY DESIGN

All cases of rhegmatogenous retinal detachment requiring drainage of SRF as part of scleral buckling surgery were considered. Specific inclusion and exclusion criteria are outlined in Table 1. Essentially, we chose eyes with retinal detachment that were not complicated by previous retinal surgery or impaired fundal view. Patients were randomised to either a DACE group or a CDAE group by the flip of a coin peroperatively. The DACE group had surgery performed using the sequence drainage, air injection, cryotherapy, and application of explant. The CDAE group had surgery performed using the sequence cryotherapy, drainage, air injection, and application of explant.

The surgery was performed either by a vitreoretinal consultant, fellow, or senior registrar. The surgical steps used were identical in all cases and differed only in their sequence—namely, DACE or CDAE. Surgery was performed either under local anterior retrobulbar anaesthesia or general anaesthesia. In the cases performed under general anaesthesia no attempt was made to reduce carbon dioxide saturation to limit choroidal vascular congestion by hyperventilating the patient.

The reported incidences of intraocular haemorrhage due to SRF drainage vary widely in the literature.[4–10] If we consider only

Table 1 Inclusion and exclusion criteria for the study

Criteria
Inclusion :
Primary surgery
Equatorial and pre-equatorial breaks
Cases requiring subretinal fluid drainage and intraocular tamponade
Exclusion:
Cases deemed unsuitable for non-drainage surgery
Secondary procedures
Retinal breaks posterior to the equator
Cases with proliferative vitreoretinopathy better treated with vitrectomy
Uncertain break localisation
Aphakes
Pseudophakes with poor fundal view

prospective studies, using needle drainage techniques akin to our own, then the incidence of IOH varies between 3.2% and 28.3%.[6 9 10] Our calculations indicate that to demonstrate a difference of this magnitude between two groups—for example, the DACE and CDAE groups, would require approximately 70 to 80 cases (power = 80%; 5% level of significance).[14]

DRAINAGE TECHNIQUE
The four recti muscles were secured with slings of 2'0 silk. Drainage of SRF was always performed using a hypodermic needle technique combined with sustained intraocular hypertension. The site for drainage was chosen always to be at the point of deepest SRF. We did not make any conscious attempt to drain just above or below the horizontal recti muscles.[3] A 27 gauge hypodermic needle, bent 2 mm at the tip, was used perpendicular to the globe to perforate the sclera and choroid in a single, controlled motion. The needle was held in situ only momentarily then removed. Digital indentation of the globe was then applied with counter tension provided by pulling on the recti slings. The indentation was applied at the most convenient position for the surgeon's access, commonly the inferotemporal quadrant, and did not necessarily coincide with the quadrant of the drainage site. The indentation and associated intraocular hypertension were observed via indirect ophthalmoscopy. Sufficient pressure was applied not only to achieve closure of the central retinal artery but also to complete blanching of the choroidal vascular bed. This pressure was maintained for 5 minutes and then eased. If bleeding was noticed then pressure was reapplied for a further 2 minutes then reassessed.

CRYOTHERAPY
Trans-scleral cryotherapy was applied to the retinal breaks. If there was any depth of SRF under the break then the cryotherapy probe was used to slowly indent the globe to approximate the retina to the retinal pigment epithelium (RPE) and disperse the fluid. We emphasise the need for sustained indentation in the cases of deep SRF to avoid excessive treatment. Cryotherapy was applied sufficient to cause freezing of the RPE and the overlying neural retinal layer.

AIR INJECTION
Intravitreal injection of air was performed via a pars plana site 3–4 mm from the limbus.

EXPLANT PLACEMENT
Circumferential or radial silicone explants were sutured to the globe using 5'0 coated Dacron mattress sutures with a spatulated needle.

DATA COLLECTION
Preoperative details such as duration of symptoms, history of trauma or ocular surgery, family history, visual acuity, refractive error, size and distribution of the retinal detachment were recorded. Peroperative details such as mode of anaesthesia, blood pressure, carbon dioxide saturation (in cases under general anaesthesia), site, and success of drainage were recorded.

If subretinal haemorrhage occurred its subretinal distribution was recorded and its size graded as less or greater than 1 disk area (<1 DA or >1 DA). Cases were reviewed at 1 day and 10 day postoperatively and any complications recorded. Final, corrected visual acuity was taken as that measured at 3 months after the primary surgery, or, in any initial failed cases, at 3 months after repeat surgery.

STATISTICAL ANALYSIS
Statistical analysis was by the calculation of the χ^2 distribution with Yates's continuity correction and one degree of freedom. In calculations where the expected cell frequencies were less than Cochrane's criterion then Fisher's exact test was used for analysis.[14]

Results

Eighty eyes of 80 patients were recruited for the study, 34 to the DACE group and 46 to the CDAE group. The patient characteristics were similar in both groups (Table 2). In particular, there were no statistically significant differences in relation to myopia greater than 6.0 dioptres, history of trauma, size and extent of retinal detachment, quadrant of drainage, or mode of anaesthesia used.

An overall anatomical success rate of 85.0% was achieved with a single operation with no statistically significant difference between the groups (DACE group = 82.4%; CDAE group = 86.9%; p = 0.38). This was improved to 98.8% following secondary procedures (DACE group = 97.1%; CDAE group = 100%).

The incidence of intraocular haemorrhage related to the drainage of SRF was low in both groups (Table 3). All the cases of intraocular haemorrhage occurred peroperatively and were managed with repeat ocular compression. In the DACE group there was only a single case of subretinal haemorrhage due to the drainage procedure (2.9 %) and this was less than 1 DA in size. In the CDAE group there were two cases of subretinal haemorrhage due to drainage (4.3%), but only one of the cases had haemorrhage greater than 1 DA in size. None of the cases of subretinal haemorrhage involved the tracking of blood beneath the macula. There was no statistically significant difference in the incidence of subretinal haemorrhage

Table 2 Patient and operative characteristics for each group

Characteristic	*DACE*	*CDAE*	*p Value*
Number	34	46	
Mean age (range)	59.3 years (14–83)	59.1 years (21–81)	0.97†
Sex ratio M:F	1.3:1.0	1.0:1.0	0.77*
Myopia > 6.0 dioptres	14.7%	19.6%	0.79*
Trauma	6.3%	9.5%	0.96*
Mean number of quadrants detached	2.3	2.2	0.53*
Macula off	61.8%	58.7%	0.96*
Quadrant of drainage			
STQ	44.1%	43.5%	0.78*
SNQ	11.8%	17.4%	0.70*
ITQ	32.3%	32.6%	0.83*
INQ	11.8%	6.5%	0.67*
Local anaesthesia	50.0%	34.8%	0.26*

*χ^2 test with Yates's continuity correction.
†Student's *t* test.
STQ = superotemporal quadrant; SNQ = superonasal quadrant; ITQ = inferotemporal quadrant; INQ = inferonasal quadrant.

Table 3 Incidence of intraocular haemorrhage associated with drainage of subretinal fluid in both groups

Characteristic	*DACE n (%)*	*CDAE n (%)*	*p Value*
Incidence of subretinal haemorrhage	1 (2.9)	2 (4.3)	0.43*

*Fisher's exact test.

Table 4 Incidence of complications in both groups

Characteristic	*DACE n (%)*	*CDAE n (%)*	*p Value*
IOH not due to drainage	1 (2.9)	3 (6.5)	0.33*
Vitreoretinal incarceration	0	1 (2.2)	0.58*
Retinal break	0	1 (2.2)	0.58*
Endophthalmitis	1 (2.9)	0	0.43*

*Fisher's exact test.

Table 5 Visual acuity outcomes for both groups

Snellen visual acuity	*DACE n (%)*	*CDAE n (%)*	*p Value*
Deterioration (≤ 2 lines)	7 (20.6)	5 (10.9)	0.13*
Stable (+/− 1 line)	9 (26.5)	15 (32.6)	0.73*
Improvement (≥ 2 lines)	18 (52.9)	26 (56.5)	0.93*

*χ^2 test with Yates's continuity correction.

In the DACE group, the 7 cases of deterioration in visual acuity included 4 cases of failed primary surgery, 2 cases of postoperative lens opacity, and 1 case of bacterial endophthalmitis. In the CDAE group, the 5 cases of deterioration in visual acuity included 2 cases of failed primary surgery, 2 cases of postoperative lens opacity, and 1 case of intraocular haemorrhage.

between the groups (p = 0.43; difference = 1.4%; 95% confidence intervals = +/− 8.2%). None of the preoperative or peroperative factors studied were found to have a correlation with the risk of IOH.

There were other incidences of IOH unrelated to the drainage procedure (Table 4). In the DACE group, there was a single case of IOH due to deep placement of an explant suture through thin sclera in a high myope. In the CDAE group there were three cases of IOH unrelated to drainage. One was due to deep placement of an explant suture, one bled from a bridging retinal vessel following cryotherapy but before drainage. A third case was observed to have had a choroidal detachment of a single quadrant postoperatively but no IOH was noted peroperatively. In addition, the quadrant of detachment was different from the quadrant of drainage. Thus, this detachment may or may not have been due to IOH. There was no statistically significant difference in the incidence of IOH unrelated to the drainage procedure between the groups (p = 0.33; difference = 3.6%; 95% confidence intervals = +/− 9.1%).

Other complications included single cases of vitreoretinal incarceration, an iatrogenic retinal break, and endophthalmitis. There were no statistically significant differences between the groups with regard to any of these complications (Table 4).

The visual outcomes were similar for both groups (Table 5). In the DACE group 26.5% had the same preoperative compared with postoperative vision (+/− 1 Snellen line) and 52.9% had an improvement (2 or more Snellen lines). In the CDAE group 32.6% had the same preoperative compared with postoperative vision and 56.5% had an improvement. There was no statistically significant difference in the visual outcome between the groups (stable vision, p = 0.73; improvement, p = 0.93).

Discussion

Drainage of SRF is an important but potentially dangerous step in the management of many cases of rhegmatogenous retinal detachment. The perforation of sclera and choroid may be complicated by IOH, retinal perforation, vitreoretinal incarceration, and endophthalmitis.[4] The most frequent complication is IOH with reported incidences of between 1.7% and 28.3%.[4–10] This can have a significant effect on visual outcome if subretinal haemorrhage tracks beneath the macula.[11]

The site chosen for drainage, the drainage technique used and whether drainage occurs before or after cryotherapy in the surgical sequence have all been implicated in influencing the risk of IOH. Many surgeons choose to drain just above or below the horizontal recti muscles in the watershed region of the vortex vein territories to reduce this risk of IOH.[3 10 13] Other surgeons adopt a technique of transillumination to avoid puncturing choroidal vessels.[15] Several different external drainage procedures have been described to reduce the incidence of IOH. These include sclerotomy with or without choroidal coagulation, choroidal perforation using sharp or blunt instruments or a laser probe, and single step sclerochoroidal perforation using a hypodermic or suture needle. Each of these techniques has advocates for its safety and efficacy.[5–10]

Several authors have suggested that performing drainage before cryotherapy might reduce the incidence of IOH by avoiding the choroidal congestion associated with cryotherapy. Gilbert and McLeod in their description of the DACE procedure state that one of the theoretical advantages of this sequence is that it could substantially reduce the risk of haemorrhage from the perforation site.[13] However, no cases of cryotherapy before drainage were described in their study. Two of their 50 DACE cases (4%) developed subretinal haemorrhage at the time of drainage, a figure similar to the 2.9% rate of haemorrhage in the DACE group in our own study. It is uncertain whether IOH less than 1 disc area in size were included in their figures. Raymond *et al* also state that the tendency to haemorrhage is dependent on the surgical sequence.[9] In their study, using a suture needle drainage technique, only 3.2% of DACE cases were complicated by IOH while 21.8% of conventional surgical cases had IOH. They do not expand on the possible reasons to account for this marked difference nor do they provide any statistical analysis of the incidence of IOH in these groups. The presumption is that the DACE sequence, specifically drainage before cryotherapy, may be responsible for the reduced incidence of IOH. More importantly in this sequence, air injection restores intraocular pressure and thus avoids haemorrhage as a result of hypotony. It can be argued that it was not the surgical sequence of drainage before cryotherapy that was significant in reducing the incidence of IOH but the lack of air injection in the conventionally treated group. A further study suggesting an effect of the surgical sequence on the incidence of IOH is that by Burton *et al* comparing hypodermic needle drainage with scleral cutdown and diathermy.[10] They found IOH occurred in 10.7% of cases where drainage was performed before cryotherapy and in 19.4% of cases of cryotherapy before drainage. This difference was not statistically significant. The cases were not randomised with respect to the sequence employed and the authors did not describe the case mix of these two sequence groups. Their needle drainage technique involved the needle being held in place until drainage of SRF was complete as described by Charles.[16] This technique is demanding requiring experience and practice. In addition, it can make the maintenance of a raised intraocular pressure difficult and hazardous owing to the risk of retinal perforation.

This study is the first controlled, prospective, randomised trial to investigate the safety and efficacy of performing drainage following cryotherapy compared with drainage before cryotherapy. We found a low incidence of IOH associated with SRF drainage whether the drainage was performed before cryotherapy (DACE group = 2.9%) or following cryotherapy (CDAE group = 4.3%). There was no statistical difference in the incidence of IOH between the two groups ($p = 0.43$). This low incidence compares favourably with previously reported incidences of IOH associated with a wide variety of drainage techniques.[4–10] We feel that a technique using a narrow gauge hypodermic needle for trans-scleral SRF drainage combined with sustained intraocular hypertension is simple to learn and to teach. If cryotherapy indeed does cause choroidal vascular congestion then its effect can be limited by complete choroidal blanching induced by digital pressure on the globe. We believe this single manoeuvre accounts for the low incidence of IOH in our study.

Our study aimed to detect a difference in the incidence of IOH between the two groups of 3.2% to 28.3%. If the incidence of IOH is 2.9% in the DACE group and 4.3% in the CDAE group then to show a significant difference the power calculations indicate we would require over 5000 cases (power = 80%; 5% level of significance). The low incidence of IOH and minimal morbidity arising from the haemorrhages in the CDAE group would not justify performing a study of this scale.

The incidence of other complications such as retinal perforation, vitreoretinal incarceration or endophthalmitis was low with no statistically significant difference between the groups. In particular, the risk of vitreoretinal incarceration which might have been increased by the use of prolonged, intraocular hypertension was limited by using a 27 gauge hypodermic needle for drainage which provided only a narrow transscleral tract. The only case of vitreoretinal incarceration was at the site of a deep scleral suture used for the application of an explant. The wider tract formed by an inadvertent deep suture needle may carry an increased risk of vitreoretinal incarceration when intraocular pressure is raised with globe indentation. This may be avoided by abandoning the use of preplaced explant sutures before drainage.

The anatomical and visual outcomes were similar in both groups. By indenting the globe with the cryotherapy probe, to approximate the neural retina to the RPE, excessive cryotherapy can be avoided. This is possible because for the purpose of this study we have confined ourselves to equatorial and pre-equatorial retinal breaks. We are conscious, particularly in the CDAE group, to prevent pigment fallout and uveitis which might promote proliferative vitreoretinopathy and affect the anatomical and visual results.[17]

Using the needle drainage technique we have described, drainage of SRF can be safely and effectively performed either before or after cryotherapy.

The use of the DACE surgical sequence has greatly improved the successful management of selected retinal detachments.[13 18] However, the visualisation of apposed retinal breaks following drainage and air injection can be difficult. Poor technique can cause multiple gas bubbles, further hindering the view. It has been pointed out that the DACE sequence can be difficult to learn and teach.[19]

The sequence of performing cryotherapy before drainage is regularly practised by some surgeons. Fitzpatrick and Abbott reported on 115 cases using scleral cutdown and argon laser for choroidal perforation. All cases had cryotherapy performed before drainage with only a 1.7% incidence of subretinal haemorrhage.[5] Although the use of the argon laser may have limited choroidal haemorrhage through the associated photocoagulation, the study does support the safety of performing cryotherapy before drainage.

For superior bullous detachments with anterior breaks the CDAE surgical sequence can be safely and effectively employed and may be an easier technique for certain surgeons. Worldwide, retinal surgeons use the sequence CDAE routinely. However, in the UK, the DACE procedure is practised more frequently, often with the presumption that the sequence of drainage before cryotherapy reduces the risk of intraocular haemorrhage.

In cases where injection is not necessary then the associated hypotony following drainage of SRF may increase the risk of IOH when subsequent cryotherapy is performed. Thus, in cases involving retinal dialysis or inferior breaks then the surgical sequence of cryotherapy, drainage and explant placement (CDE) may be effective and safe.

We conclude that the use of cryotherapy before SRF drainage can be safely performed and that the sequences CDAE and CDE along with DACE should be part of our surgical repertoire for the management of retinal detachments.

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